EXHIBIT J

Trace Evidence Unit
Validation of Technical Procedures

1 Introduction

Forensic laboratories must implement procedures to ensure that a selected analytical protocol is capable of producing accurate and reliable results. To demonstrate the performance of a technical procedure, a validation study is performed. A validation study involves evaluation of specific analytical parameters, such as accuracy and/or limit of detection. The Trace Evidence Unit (TEU) will define an acceptable range for each of the parameters evaluated. When the selected parameters of an analytical method have been demonstrated to fall within the acceptable ranges and appropriately reviewed, the method is considered validated and can be adopted into the TEU's standard operating procedures for routine use. This document provides guidelines for the development and validation of new analytical procedures in the TEU.

2 Scope

This document applies to all new technical procedures developed and/or implemented in the Trace Evidence Unit. The performance characteristics that are evaluated will be based on the requirements of the analytical procedure.

3 Documentation

All documentation related to instrumental validation studies conducted within the TEU will be maintained with the instrument log books for that instrument. All documentation related to method validation will be kept as a separate file with other quality assurance records for the TEU. This includes any relevant journal articles, instrument optimization charts, or validation data used or generated as part of the validation study.

4 Validation Process

Validation is performed under the direction and management of an appropriate Technical Leader. The process of validating a technical procedure should occur stepwise as follows:

4.1 Define the scope of the analytical procedure.

4.2 Identify the characteristic(s) of the technical procedure to validate.

4.3 Optimize analytical parameters and select experiments to determine the required characteristic(s).

4.3.1 Standardized Technical Procedures

A standardized analytical procedure has been documented, validated, and endorsed by a recognized technical organization (e.g., ASTM, AOAC, EPA, USP, etc.). In this case, the sample preparation and instrumental parameters have been established, so the only experiments required are those that will demonstrate that the technical procedure can be duplicated within the TEU and that similar performance characteristics can be achieved.

4.3.2 Modified Standardized Technical Procedures

A modified standardized technical procedure is one that has been modified outside the specifications of the standardized procedure. In this case, it must be verified that the modifications do not alter the performance characteristics such that the data are no longer appropriate for the intended purpose.

4.3.3 Non-standardized Technical Procedures

A non-standardized technical procedure has been developed externally but has not been previously endorsed by a recognized technical organization (e.g., an analytical procedure published in a technical journal). In this case, the performance characteristics applicable to the intended purpose must be determined and appropriate validation experiments must be conducted.

4.3.4 In-house Technical Procedures

An in-house technical procedure is developed within the TEU for subsequent routine use or as a solution to a unique analytical problem. In this case, the performance characteristics applicable to the intended purpose must be determined and appropriate validation experiments must be conducted.

4.4 Conduct experiments to determine the required characteristic(s).

4.5 Technical Review and Approval

Upon completion of the method development and/or validation the Unit Chief will assign at least one appropriate Technical Leader as a reviewer of the validation results. If the Unit Chief is a Technical Leader qualified in the appropriate area of expertise, he/she may perform the technical review. After the technical review is complete, documentation of the technical review and approval of the method will be on a final copy of the validation study as follows:

Technical Reviewer: _____ Date: _____

5 Competency Testing

All examiners/physical scientists/technicians must be competency tested on a newly validated analytical procedure before they use it in casework.

6 Procedure Modifications

There are times when deviating from an established standard operating procedure is necessary. When a deviation occurs, the step-by-step procedures that were used must be documented as stated in section 3, as well as the appropriate approval for deviation as follows:

6.1 Significant Modifications to Previously Validated Procedures

If a significant modification has been made to a previously validated procedure, at a minimum, the modification will be evaluated by comparison of established results with those generated by the current procedure using appropriate samples. These modifications should produce results of the same or improved quality as compared with those obtained by the previously validated procedure. Significant modifications documentation and approval will be done in accordance with major deviation requirements set forth in the FBI Laboratory Operations Manual, Practices for Authorizing Deviations. Any deviations to procedures must be approved by an appropriate Technical Leader prior to their submission to the Quality Assurance and Training Unit.

6.2 Minor Modifications to Previously Validated Procedures

A minor modification to an existing procedure that does not materially affect the performance of the test does not require additional validation studies. These modifications should improve the efficiency, effectiveness, and/or quality of the test. Minor modification documentation and approval will be done in accordance with minor deviation requirements set forth in the FBI Laboratory Operations Manual, Practices for Authorizing Deviations.

7 References

- FBI Laboratory Quality Assurance Manual.
- FBI Laboratory Operations Manual.

Rev. #	Issue Date	History
0	07/10/06	Original issue.
1	05/17/11	Section 1, changed "should" to "will". Section 3, storage location of validation documentation changed. Section 4, 4.5, and 6.1 changed to add Technical Leader to review process. Section 6.1 and 6.2, edited wording of sections.

Approval

TEU Chief: _____ Date: 05/16/2011
Cherise B. Dreyfus

QA Approval

Quality Manager: _____ Date: 05/16/2011
Catherine E. Theisen

Issuance

TEU QA Manager: _____ Date: 05/16/2011
Joshua D. Friedman